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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/049,847 03/27/98 BAY

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EXAMINER

WESSENDORF, T

ART UNIT

PAPER NUMBER

1618

13

DATE MAILED:

08/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/049,847

Applicant(s)
Bay et al

Examiner
T. Wessendorf

Group Art Unit
1618



☒ Responsive to communication(s) filed on May 4, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 15, 16, and 26-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 and 17-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicants' election of Group I, claims 1-14 and 17-19 in Paper No. 6 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 20-25, drawn to compositions and method of using the conjugate would be examined with the elected claims. However, newly submitted claims 26-28 are drawn to an invention (antibodies)(II) that is independent or distinct from the invention originally claimed (conjugate)(I) for the following reasons: Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product, conjugate, is deemed to be useful in the different claimed methods of using said conjugate e.g., claims 22-25 or to make other glycopeptide conjugate useful as anti-viral agent and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious

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variants. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 15-16 and 26-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Claim 18 which was included in Group II in the Restriction of 12/21/98 is not withdrawn from consideration. A PRELIMINARY AMENDMENT submitted on 10/9/98 amended the dependency of claim 18 to depend only on claim 1. Therefore, claims 1-14, 17-19 and 20-25 are pending in the application.

New formal drawings are required in this application because of the reasons set forth in PTO 948. Applicants are advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

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INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36**

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

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All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

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Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicants desire priority under 35 U.S.C. 119(e) based upon a previously filed provisional application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

The format of the references provided in the specification e.g., at page 2, line 5 which merely assigns R numbers e.g. (Ref. 3c, Ref. 4) to the numerous cited references is not a proper format. It is suggested that applicants supply the complete citations for each of the cited references. For example, if the reference is a U.S. Patent, the Patent number should be supplied, if a publication, the journal name, publication date etc. Furthermore, if applicants desire said references to be considered by the examiner, "the list may not be incorporated

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into the specification but must be submitted in a separate paper" as required by 37 CFR 1.98(b). MPEP § 609 A(1). Note the list of references provided at pages 31-35 of the instant specification. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;

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- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities:

A). There is no Sequence Identifier No. for the sequence KLFVWKITYKDT at page 28, lines 22 and 26.

B). Grammatical and typographical errors too numerous to mention specifically. Examples of grammatical errors are: "an composition" at page 4, line 24 (should be --a--); "between two and eight" at page 8, lines 11 and 13 (" and" should be --to--). Examples of typographical errors: 'developped' and 'complet' at page 28, line 10 and line 27, respectively.

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The use of the trademark TWEEN 20 at page 21, line 17 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 7, 19 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 19, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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Claim 7 recitation of T type is unclear as to the type of T intended to convey. The addition of the word "type" to an otherwise definite expression extends the scope of the expression so as to render it indefinite. Ex parte Copenhaver, 109 USPQ 118 (Bd. App. 1955); Ex parte Attig, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986). See MPEP 2173-05(e).

The recitation in Claim 5 with the carbohydrate "forming a B epitope" is unclear. It is not clear as to how the B epitope is formed. Cf. with claim 1 which recites that the carbohydrate contains B epitope. It is suggested that applicants delete the term "forming".

Claim 1, line 8 merely recites "epitope". It is suggested that applicants recite a B epitope to provide proper antecedent basis from the preceding recitation that the carbohydrate is a B epitope and for consistency in the claim, especially since there is more than one epitope being claimed.

The term 'in particular' in claims 22 and 23 in combination with the conjunction "and/or" renders the claim indefinite. It is not clear how the enhancement responses are achieved either by B or T alone, especially in the absence of positive showing or recitation in the specification.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 12-13, 17-18 and 22-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lett et al (Infection and Immunity).

Lett discloses e.g., at page 2646, col. 1, Materials and Methods, a carbohydrate peptide conjugate comprising a carrier, a dendrimeric polylysine, attached thereto eight identical T epitope peptides organized as (VAPNYEKEPT)_n-(Lys)₄-(Lys)₄-CONH₂ and a carbohydrate T-cell independent moiety i.e., a mixture of natural polysaccharide obtained from Streptococcus and

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Saccharomyces. Therefore, the specific carbohydrate peptide conjugate of Lett containing specific carbohydrate and peptide components for the conjugate anticipates the claimed carbohydrate peptide conjugate broadly containing at least one carbohydrate and at least one peptide component. Furthermore, the disclosure of Lett that the carbohydrate moiety is a T-cell independent epitope would have inherently or obviously indicated that the carbohydrate moiety is a B cell epitope inasmuch as the conjugate induces a strong antibody responses. These strong antibody response would have originate from the antigenic carbohydrate which is known to inherently induce little or weak T-cell responses. The claimed carbohydrate peptide conjugate wherein the carbohydrate moiety is a B cell epitope appears to be the same or similar to the prior art carbohydrate peptide conjugate wherein the carbohydrate is stated to be T-independent, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the instant and prior art carbohydrate peptide conjugate with the carbohydrate being a B cell epitope and that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the

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claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is upon the applicants to prove that the claimed carbohydrate B-cell epitope containing conjugate is functionally different from those taught by the prior art and to establish patentable differences. See in re Best 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (BPAI 1989).

Claims 1-5, 10-11, 17-19, 22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lett in view of Tam [5,229,490(I) or 5,580,563(II)].

Lett is discussed, supra. Lett fails to disclose a carbohydrate conjugate with several different T cell epitope peptide or B cell carbohydrate attached to the core polylysine as claimed in claim 1 and the T epitope as being a VP1 protein of poliovirus type 1 as claimed in claim 10 or CD8+T cell epitope as recited in claim 11. However, Tam (I) discloses e.g., at col. 6, lines 10-50; col. 7, Table 1 up to col. 8, line 8 and col. 9, lines 4-18 that conjugates with several identical or different antigenic products of T-cell antigens and B-cell antigens joined to a dendritic polylysine would generate extremely high antibody titers. Furthermore, Tam (I) at col. 7, Table 1, lines 25-26 positively discloses poliovirus as one of the antigenic products.

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Tam (II) basically discloses e.g., at col. 5, line 25 up to col. 6, line 4 a similar conjugate as Tam (I). Tam(II) further discloses e.g., at col. 12, lines 44-49 that a dendrimeric polylysine peptide conjugate elicits CD8+ T-cell responses against the gp 160 of HIV. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the several identical T-cell epitope peptide (or B-cell) carbohydrate in the conjugate of Lett with several different T-cell peptide (or B-cell) carbohydrate components with a reasonable expectation that the different T-cell peptide (or B-cell) antigen carbohydrate components would generate or function in a similar manner as the conjugate containing several identical T (and B) cell antigens i.e., high antibody titers as disclosed by Tam. Furthermore, it would have been obvious to use poliovirus T-cell peptide antigen in the as the peptide antigen in the conjugate of Lett since Tam(I) positively teaches conjugation of said poliovirus to the polylysine and that the said conjugate would expectedly elicit high antibody titers against the virus, as with any antigen containing the polylysine carrier. Likewise, it would have been obvious to use CD8+ as the T-cell epitope peptide antigen as the peptide antigen in the conjugate of Lett since Tam (II) discloses

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that CD8+ lyses synegenic cells of the gp160 HIV which neutralizes the infectivity of said HIV that will lead to the development of synthetic HIV vaccine. It would be prima facie obvious to select the type of antigen that can be attached to the polylysine as per the suggested teachings of Tam (I) that different kinds of antigen can be attached to the polylysine and provides a list of some of these antigenic determinants.

Claim 17-19 are rendered obvious by the disclosure of Tam (I) which positively teaches the specific components comprise in a vaccine, immunogenic or pharmaceutical composition. See e.g., at col. 9, line 50 up to col. 10, line 51. Claim 19 is obvious in view of the disclosure of Tam (I) at col. 7, lines 54-59 which recites the immunogenic composition as being able to elicit immune response against hepatitis virus. The HIV antigen is recited at Table 1, col.7, line 15.

Claims 6-9, 14 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lett in view of Tam as applied to claims 1-5, 10-11, 17-19, 22 and 24-25 above, and further in view of Fung et al (Cancer Research).

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Lett does not disclose the polysaccharide as containing galactose residue as claimed in claim 6, specifically the 4- α -galactosyl-N acetyl-Ser residues as in claim 7 and the carbohydrate antigen as a tumor antigen as claimed in claim 9. However, Fung discloses e.g., at page 4308, col. 1 up to page 4313 synthetic polysaccharide tumor antigen containing 4- α -galactosyl-N acetyl-Ser residues attached to protein Keyhole limpet hemocyanin. The said tumor antigen is considered to be an important human tumor marker against which an antitumor immune response could be induced. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the polysaccharide antigen in the conjugate of Lett with a polysaccharide antitumor antigen since said carbohydrate antigens when conjugated to a carrier has been shown to be an important human tumor marker against which an antitumor immune response could be induced, as taught by Fung.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Longenecker et al discloses immune responses of mice and human breast cancer patients following immunization with synthetic Sialyl-Tn conjugated to KLH.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 6:30 to 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7942.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

tdw

8/2/99

T. D. Wessendorf
Patent Examiner